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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,028	03/25/2004	Michael Bennett	020714-002410US	9644

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EXAMINER	
KELLY, ROBERT M	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,028	BENNETT ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-34 are presently pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-23 and 34, drawn to a method of attenuating increases in radiation-induced free radicals or superoxide anions in a mammalian cell, comprising the administration of at least one nucleic acid encoding at least one protein, a pluriality of salivary gland cells comprising the nucleic acids, and specific nucleic acids utilized in the methods, classified in class 514, subclass 44.

II. Claims 2-23 and 34, drawn to a method of attenuating increases in heavy metal cations in a mammalian cell, comprising the administration of at least one nucleic acid encoding at least one protein, a plurality of nucleic acid comprising the nucleic acids, and specific nucleic acids utilized in the method, classified in class 514, subclass 44.

III. Claims 24-26, drawn to a method of ameliorating xerostomia in a mammal, comprising administering 1 of 12 compositions comprising proteins, classified in class 530, subclass 351.

IV. Claims 27-33, drawn to a method of ameliorating xerostomia in a mammal, comprising administering a nucleic acid encoding an IFN-alpha protein, classified in class 514, subclass 44.

Claims 1 link(s) inventions I and II. The restriction requirement of the linked inventions is subject to the nonallowance of the linking claim(s), claims 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01. The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, and have distinct steps, which require distinct search and examination considerations. To wit, group I requires a consideration of the scope of nucleic acids which may encode the specific proteins, and how to administer such to obtain attenuation, group II requires a consideration of the scope of nucleic acids which may encode proteins which decrease heavy metal cations, and how to administer these nucleic acids to obtain such attenuation, group III requires a consideration of the scope of IFN-alpha proteins, and how to administer such to obtain amelioration of a symptom of

xerostomia, and group IV requires a consideration of the scope of nucleic acids which may encode an IFN-alpha and be administered to obtain amelioration of a symptom of xerostomia. Hence, due to the distinct considerations for each group, the search and examination burden to search and examine any two groups together would pose a serious burden.

It is further noted that groups I-II and IV are all classified in 514/44, however such class if broad, encompassing all gene therapy, and hence, the search and examination within this class would necessarily be distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In addition, **if groups I or II are elected**, this application contains claims directed to the following patentably distinct species of the claimed invention:

(a) Applicant is required to choose a single protein from the group consisting of metallothionein, catalase, glutathione peroxidase, gamma glutamyl transpeptidase, copper-zinc superoxide dismutase, manganous superoxide dismutase, or iron superoxide dismutase (Claims 2-8);

(b) Applicant is required to choose a single expression vector, **within the scope of the chosen protein of (a),** from SEQ ID NOs 1-8 (Claim 17);

(c) Applicant is required to choose administration of the expression of the vector, prior to, or after, irradiation with X-rays, as well as a salivary or lacrimal cell (Claims 12-15);

If group III is elected:

(d) Applicant is required to choose one of the twelve protein compositions of claim 24 (it is noted that the Examiner believes the combination of IL-4 and VIP to be a single composition, if such is incorrect, Applicant must explain such in the response);

If group IV is elected:

(e) Applicant is required to choose one of the 14 disorders of claim 28;

(f) Applicant is required to choose one of the two body fluids in claims 30-31.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, for each of (a)-(f), above, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 4, 9, 10, 11, 16, 17, 24, 27, 28, 29, and 34 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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